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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,977	05/02/2007	**Haijun Sun**	X-18530	2166

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EXAMINER	
DEBERRY, REGINA M	

ART UNIT	PAPER NUMBER
1647	

NOTIFICATION DATE	DELIVERY MODE
08/06/2010	ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

patents@lilly.com

Office Action Summary	Application No.	Applicant(s)	
	10/575,977	SUN ET AL.	
	Examiner	Art Unit	
	Regina M. DeBerry	1647	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 May 2010*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *60-67* is/are pending in the application.

4a) Of the above claim(s) *62-64* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *65-67* is/are rejected.

7)☒ Claim(s) *60 and 61* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *3/9/10,5/18/10*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Status of Application, Amendments and/or Claims

The amendment and Applicant's arguments, filed 17 May 2010 and 18 May 2010, have been entered in full. Claims 1-59 are canceled. Claims 62-67 are withdrawn from consideration as being drawn to a non-elected invention.

Claims 60 and 61 are directed to an allowable product, but have a minor informality (see below).

Pursuant to the procedures set forth in MPEP § 821.04(b), claims 65-67, directed to the process of making or using the allowable product, previously withdrawn from consideration as a result of a restriction requirement, are hereby rejoined and fully examined for patentability under 37 CFR 1.104. Claims 62-64, directed to the invention(s) of the nucleic acid encoding the antibody, expression vector and host cell, do not require all the limitations of an allowable product claim, and have NOT been rejoined.

Because a claimed invention previously withdrawn from consideration under 37 CFR 1.142 has been rejoined, **the restriction requirement between Groups I and V-VII as set forth in the Office action mailed on 05 October 2009 is hereby withdrawn**. In view of the withdrawal of the restriction requirement as to the rejoined inventions, applicant(s) are advised that if any claim presented in a continuation or divisional application is anticipated by, or includes all the limitations of, a claim that is allowable in the present application, such claim may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Once the restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 443 F.2d 1211, 1215, 170 USPQ

129, 131-32 (CCPA 1971). See also MPEP § 804.01. Claims 60, 61 and 65-67 are under examination.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 67 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The instant claim is indefinite because of the recitation, "a method of reducing food intake ***or a condition affected by reducing food intake***..". It is unclear what a method of reducing a condition affected by reducing food intake encompasses as the specification fails to teach such method or such conditions. The metes and bounds of the instant claim cannot be determined.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 65 and 67 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for:

a method of treating obesity comprising administering to a mammal in need thereof a therapeutically effective amount of the antibody or antigen binding fragment of claim 60, **wherein food intake is reduced to treat obesity** (claim 65)

or

a method of reducing food intake comprising administering to a mammal in need thereof a therapeutically effective amount of the antibody or antigen binding fragment of claim 60 (claim 67)

does not reasonably provide enablement for:

a method of treating obesity comprising administering to a mammal in need thereof a therapeutically effective amount of the antibody or antigen binding fragment of claim 60

or

a method of reducing food intake **or a condition affected by reducing food intake comprising** administering to a mammal in need thereof a therapeutically effective amount of the antibody or antigen binding fragment of claim 60

The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

The specification teaches the variable heavy chain of FR1-A1 as SEQ ID NO:15 and the variable light chain of FR1-A1 as SEQ ID NO:16 {i.e. FGFR1(IIIc) antibody} (page 3, para 10). The specification teaches that the FR1-A1 antibody caused weight loss and reduced food intake in mice (page 38, para 134 and Figures 24 and 25). The specification is not enabling for the full scope of the instant claim because the state of the art establishes a range of underlying mechanism for obesity treatment. For example, Henness et al. (Drugs, 66/12:1625-1656, 2006) teach that Xenical treats obesity *by inhibiting dietary fat absorption*. Gangwisch (Obesity Review, 10/s2:37-45, 2009) suggest that improved quality of sleep can be used to treat obesity *by*

lowering cortisol levels. Lastly, while the specification teaches reduced food intake in mice upon administered FR1-A1 antibody, the specifications fails to teach a method of reducing a condition affected by reducing food intake. It is unclear how one skilled in the art reduces a condition and the instant specification fails to teach what reduced conditions are affected by reduced food intake.

Due to the large quantity of experimentation to treat obesity by any biological mechanism, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, and the breadth of the claims which fail to recite limitations regarding the mechanism to achieve the recited goal, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention in its full scope.

Claim 66 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The instant claim is not supported by an enabling disclosure because the specification fails to teach that FR1-A1 {FGFR1(IIIc) antibody} has any affect on glucose levels or can be used to treat any element of diabetes. For example, Xia (Redai Yixue Zashi 5/5:713-714, 2005) and van der Laar et al. (Diabetes research and clinical practice 63/1:57-65, 2004) both teach assays such as measuring fasting blood glucose levels and insulin levels in patients to discern the

therapeutic effects of a pharmaceutical for treating diabetes. No such test were employed for the FR1-A1 antibody.

Due to the large quantity of unpredictable experimentation necessary to employ the FR1-A1 antibody in the treatment of diabetes without knowing its effect on glucose and/or insulin levels, the lack of direction/guidance presented in the specification regarding same, the absence of working examples directed to same, the complex nature of the invention, and the state of the art which establishes the effectiveness of a therapeutic for treating diabetes is discerned by employing fasting blood glucose and insulin levels assays, undue experimentation would be required of the skilled artisan to make and/or use the claimed invention.

Claim 67 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. **This is a new matter rejection.**

The specification as originally filed does not provide support for the invention as now claimed: ""a method of reducing food intake ***or a condition affected by reducing food intake***.."

Applicant's amendment, filed 02 November 2009, asserts that no new matter has been added and directs support to page 21, paragraph 82 and page 38, Example 16 for the written description for the above-mentioned "limitations".

The Examiner has located a teaching of a method of reducing food intake on page 21, paragraph 82. The Examiner cannot find a teaching of a method of reducing a condition affected

by reducing food intake. The wording or connotation of the instant claim(s) is not readily apparent from said sections.

The specification as filed does not provide a written description or set forth the metes and bounds of this "limitations". The instant claims now recite limitations which were not clearly disclosed in the specification as filed, and now change the scope of the instant disclosure as-filed. Applicant is required to cancel the new matter in the response to this Office action. Alternatively, Applicant is invited to provide specific written support for the "limitations" indicated above or rely upon the limitations set forth in the specification as filed.

Claim Objections

Claims 60 and 61 are objected to because of the following informalities: Claim 60 should recite, "**A** purified.." instead of "**An** purified..". Appropriate correction is required. Claim 61 is objected to because it depends from an objected claim. The Examiner notes that amending claim 60 will obviate the instant objections, thus rendering claims 60 and 61 allowable.

Conclusion

Claims 65-67 are rejected.

Claims 60 and 61 are objected to.

No claims are allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Regina M. DeBerry whose telephone number is (571) 272-0882. The examiner can normally be reached on 9:00 a.m.-6:30 p.m.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary B. Nickol can be reached on (571) 272-0835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Marianne P. Allen/
Primary Examiner, Art Unit 1647

/R. M. D./
Examiner, Art Unit 1647
7/29/10